US ERA ARCHIVE DOCUMENT



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 8 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

6(A)(2) DATA

SUBJECT: SULFURYL FLUORIDE. ID NO. 078003. Chronic

Neurotoxicity Study in Rat.

Tox. Chem. No.: 816A
PC No.: 078003
Submission No.: S465860
Barcode No.: D203513

FROM: Linnea J. Hansen, Ph.D. Kuma Thomas

Section IV, Tox. Branch I 6/2/54

Health Effects Division (7509C)

TO: Larry Schnaubelt, Manager, PM Team 72

Robert Richards, Reviewer, PM Team 72

Special Review and Reregistration Division (7508W)

THRU: Marion P. Copley, D.V.M., D.A.B.T., Section Head

Section IV, Tox. Branch I

Health Effects Division (7509C)

Karl Baetcke, Ph.D., Branch Chief

Tox. Branch I

Health Effects Division (7509C)

## CONCLUSIONS:

Based on a preliminary review of the 6(a)(2) rat chronic inhalation neurotoxicity data on sulfuryl fluoride, TB-I has determined that the results of this study do not change the toxicity endpoints used for risk assessment of inhalation exposure to sulfuryl fluoride. The neurotoxicity NOEL for this study is ≥80 ppm (based on functional observational battery, motor activity and histopathology) and the systemic toxicity NOEL for chronic inhalation exposure is 5 ppm. The neurotoxicity NOEL is therefore greater than the NOEL of the previously submitted 90-day study (30 ppm based on electrophysiological effects at 100 ppm. MRID no. 408399-02; reviewed in HED doc. no. 009479). The systemic toxicity NOEL is the same as the NOEL of the reproduction study in rat (5 ppm) and is based on the same effect (mottling of the teeth due to fluorosis at 20 ppm).

A subordinate bean has been generated for complete



evaluation of the submitted study (D204025, S465860). The study will be reviewed in a timely fashion but not on an expedited basis since the chronic inhalation neurotoxicity data does not indicate an imminent hazard or affect the toxicologic endpoints used for exposure risk assessment.

## ACTION REQUESTED:

On April 29, 1994, DowElanco submitted for review, as 6(a)(2) data, a chronic inhalation neurotoxicity study on sulfuryl fluoride (MRID 432167-02). The neurotoxicity testing was conducted using satellite groups in a chronic inhalation study to fulfill Guideline 82-7 (90-day neurotoxicity testing in rat) by assessing some parameters not included in the previously submitted 90-day neurotoxicity study in rat.

CC: Flora Chow, CCB/HED